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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/631,241	08/02/00	MARGOLIN	A VPI96-1400N
			EXAMINER
001473 HM12/1004 FISH & NEAVE 1251 AVENUE OF THE AMERICAS 50TH FLOOR NEW YORK NY 10020			
			1651
			DATE MAILED: 10/04/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 9/2/00
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-85 is/are pending in the application.
- ☐ Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-85 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

This application is a continuation of parent application 08/834,661, now abandoned.

Claims examined on the merits are 1-85 which are all claims in the application.

5 Claims 1-60, 76-77 and 80-85 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for crosslinking with a multifunctional crosslinking agent, does not reasonably provide enablement for other crosslinking agents. The specification does not enable any person skilled in the art to which it
10 pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification demonstrates the use of only a multifunctional crosslinking agent and does not describe steps and conditions for other forms of crosslinking.

15 Claims 30, 31, 39-44, 67-75 and 80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

20 In claims 30 and 40, the meaning of "decontamination proteins" is uncertain.

In the last line of claim 31, it is uncertain as to vitamins that are a protein.

 Claims 39-44 are unclear as to how they further limit claims 1, 17 or 18 by requiring a delivery system since the system is required to
25 contain only the crosslinked protein of claims 1, 17 or 18.

In claims 67-75, it is unclear as to the substance that contains the percentages of crosslinking agent and the basis of the percentages.

Claim 80 is unclear as to how it differs from claim 76. If these are the same, one should be deleted.

5 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

10 (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-44, 46-63, 76 and 80-85 are rejected under 35 U.S.C. 102(a) as anticipated by Navia et al (5,618,710).

15 The claims are drawn to crosslinked protein crystals and methods for preparation thereof wherein the crosslinked protein crystals can be changed from insoluble form to soluble form by a change in temperature, change in pH, change in chemical composition, change from concentrate to dilute form or change in shear force acting on the crystal.

20 Navia et al disclose crosslinked protein crystals that are inherently capable of being changed to soluble form by one or more of the changes claimed. The present claims encompass crosslinked protein crystals and methods for preparation thereof disclosed by Navia et al.

25 Applicants have urged in the parent application that Navia et al produce crosslinked protein crystals that do not dissolve under harsh conditions. However, the present specification discloses (page 9, lines 13-15) that the crosslinked crystals of the invention are stable to harsh conditions imposed by the formulations or compositions in which they are

employed or conditions of storage. Additionally, in the present specification, in example 18, the final crosslinker concentration is 4%, and crosslinking is carried out for 24 hours. These conditions appear to be also used in examples 19 and 20. In example 22, 6.5% glutaraldehyde is used and in example 23, 6.0% glutaraldehyde is used. These are the type of crosslinking conditions that can be used by Navia et al. Note that in example 4, 5.77% glutaraldehyde is used and in example 9 (col 48, line 40), 2% glutaraldehyde is used. If the crosslinking conditions can be the same or essentially the same, the presently claimed crosslinked crystals must be the same or essentially the same.

Applicants in the parent application referred to tables V and VI as showing a comparison between crosslinked crystals prepared according to Navia et al and according to the invention. However, it is unclear from the tables as to the difference in procedures used to prepare the crosslinked crystals of the invention as compared to those of Navia et al. The present claims do not require crosslinking conditions significantly different than can be used by Navia et al.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the

contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential
5 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 45 and 64-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Navia et al.

It would have been obvious to use a crosslinked enzyme crystal such as a protease produced as disclosed by Navia et al in a detergent
10 formulation as required by claim 45 since it is conventional to use enzymes such as proteases in detergent formulations and Navia et al disclose using crosslinked enzyme crystals for uses where enzymes are conventionally used.

It would have been a matter of obvious choice to use known
15 crosslinking agents other than disclosed by Navia et al as in claims 64-66 since the other crosslinking agents would be expected to provide crosslinked protein crystals.

Using amounts of crosslinking agent less than used by Navia et al as in claims 67-75 would have been obvious when a longer time is used for
20 crosslinking. Using a combination of crosslinking agents as in claims 74-75 would have been obvious to obtain the functions of different crosslinking agents together.

Claims 1-62 and 76-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Navia et al in view of Kausch et al (5,508,164), and if
25 necessary in further view of Neville et al (5,066,490).

Claims 77-79 require a reversible crosslinking agent which can be a disulfide crosslinking agent.

Kausch et al disclose using disulfide crosslinking agents for reversible immobilization (col 6, lines 52-68).

5 Neville et al disclose using a reversible crosslinking agents for linking an amino group containing substance to a group on a second compound so the crosslinking agent can be cleaved to release the substance.

10 It would have been obvious to use a disulfide crosslinking agent as the crosslinking agent of Navia et al to obtain reversible immobilization as disclosed by Kausch et al. If needed, Neville et al would have further suggested a reversible crosslinking agent and that the agent can be other than a disulfide crosslinking agent.

15 Applicants urged in the parent application that Kausch et al crosslink to immobilize. However, crosslinking protein crystals is a form of immobilization. It would have been obvious to release a protein from the crosslinked protein crystals of Navia et al for the same reason that Kausch et al release a protein crosslinked to a support and Neville et al release a crosslinked biologically active substance.

20 Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

25 If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

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Art Unit: 1651

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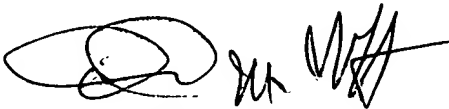
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 305-3014 or 308-4242.

5 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

10

DMN
10/2/00


DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651